



Optimal Exposure of Fludarabine in Patients with Chronic Lymphocytic Leukemia

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ABOUT THE STUDY

Fludarabine is a chemotherapy drug used to treat hematologic malignancies. It is commonly sold under the brand name Fludara. Fludarabine injections can reduce the number of blood cells made in the bone marrow. Fludarabine is a synthetic adenine nucleoside analog used in first- and second-line treatment of Chronic Lymphocytic Leukemia (CLL). Fludarabine belongs to a group of drugs called antimetabolites. This drug is used in CLL patients who have already been treated with alkylating agents (such as bendamustine) that are not working well. Fludarabine interferes with the growth of cancer cells that are eventually destroyed. Other effects may also occur, as the drug can also affect normal cell growth. Some of these can be serious and should be reported to the doctor. Other effects may be less severe but may be cause for some concern.

Some side effects may occur after stopping treatment with fludarabine. In addition to the desired effects, drugs can have some unwanted effects. Not all of these side effects occur, but if they do, you may need to consult the health care professionals immediately. Side effects caused by fludarabine include arm, back, or jaw pain, blood in the urine, chest pain, tightness or heaviness in the chest, constipation, cough or hoarseness, cough or hematemesis, rapid or irregular heartbeat, fever or chills, feeling unwell, pain in the lower back or side, nausea, tingling, pain, burning or difficulty urinating, pale skin, red patches on the skin, shortness of breath.

The recommended adult dose of fludara (fludarabine) for injection is 25 mg/m² administered intravenously over approximately 30 minutes daily for 5 consecutive days. Each treatment cycle of 5 days should start every 28 days. The dose may be reduced or delayed based on evidence of hematologic or

non-hematologic toxicity. Physicians should consider delaying or stopping drug administration if neurotoxicity occurs. If this medicine comes in contact with the skin, wash it off immediately with soap and water. In case this drug is contacted with the eyes, open the eyelids and rinse with water. Drug interactions can change how a drug works or increase the risk of serious side effects. Products that may interact with this drug include "blood thinners" (warfarin, enoxaparin, etc.), live vaccines (nasal flu vaccines, oral typhoid/polio vaccines, etc.), and pentostatin. Weaken blood immune system/increased risk of infection (eg. natalizumab, rituximab), salicylates/NSAIDs (eg. aspirin, ibuprofen, and naproxen). This drug may cause temporary hair loss in rare cases. When you stop treatment with fludarabine, your hair should return to normal. Up to 6 cycles lasting about 6 months in total can be used if desired.

Fludarabine is highly effective in treating chronic lymphocytic leukemia, producing higher response rates than alkylating agents alone, such as chlorambucil. Fludarabine is used in various combinations with cyclophosphamide, mitoxantrone, dexamethasone, and rituximab to treat indolent non-Hodgkin lymphoma. Blood tests will be done before and during treatment. It checks the levels of blood cells and other substances in the blood. It also checks liver and kidney function. The doctor will adjust the dose according to how well the treatment works. If side effects are severe, the dose can be reduced or treatment stopped. It is important to take each dose of this medicine as planned. Keep all medicines out of reach of children and pets. Do not flush medications down the toilet or the drain. Properly dispose of this product when expired or no longer needed. Laboratory or medical tests (such as a complete blood count) should be performed regularly to monitor progress and check for side effects.

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